

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE: XARELTO (RIVAROXABAN) ('310)
PATENT LITIGATION

MDL NO. 21-MD-3017-RGA-LDH

BAYER INTELLECTUAL PROPERTY
GMBH, BAYER PHARMA AG, BAYER AG,
and JANSSEN PHARMACEUTICALS, INC.,

Plaintiffs,

C.A. No. 24-336-RGA

V.

PRINSTON PHARMACEUTICAL, INC.,

Defendant.

BAYER PHARMA AG, BAYER AG and
JANSSEN PHARMACEUTICALS, INC.,

Plaintiffs,

V.

C.A. No. 21-314-RGA-LDH
(Consolidated)

LUPIN LIMITED, et al.

Defendants.

STIPULATION AND ORDER REGARDING CONSOLIDATION AND SCHEDULE

WHEREAS, Plaintiffs Bayer Intellectual Property GmbH, Bayer Pharma AG, Bayer AG, and Janssen Pharmaceuticals, Inc. (collectively, “Plaintiffs”) filed C.A. No. 24-336-RGA against Defendant Princeton Pharmaceutical, Inc. (“Princeton”) in connection with Princeton’s submission of an Abbreviated New Drug Application (“ANDA”) to the U.S. Food and Drug Administration

seeking, inter alia, approval for a generic version of Plaintiffs' 2.5 mg Xarelto[®] product prior to the expiration of U.S. Patent No. 10,828,310 ("the '310 patent")¹; and

WHEREAS, Plaintiffs are engaged in related litigations against a number of defendants in connection with the '310 patent, which are coordinated and consolidated under MDL No. 21-3017-RGA and C.A. No. 21-314-RGA-LDH (consolidated), which is currently stayed pending final resolution of the appeal of *Mylan Pharmaceuticals Inc. et al. v. Bayer Pharma AG*, IPR2022-00517 (PTAB), *see Bayer Pharma Aktiengesellschaft v. Mylan Pharms. Inc.*, No. 2023-2434 (Fed. Cir.); and

NOW, THEREFORE, Plaintiffs and Princeton hereby STIPULATE, and request that, with respect to all claims related to the '310 patent, the Court ORDER, as follows:

1. All claims related to the '310 patent pending in C.A. No. 24-336-RGA shall be consolidated with C.A. No. 21-314-RGA-LDH (consolidated) for all purposes, including for trial. All papers concerning claims related to the '310 patent shall be filed in C.A. No. 21-314-RGA-LDH (consolidated).

2. The Court's Orders staying the case in C.A. No. 21-314 ("Stay Orders," D.I. 144, 153) shall apply to all claims related to the '310 patent in C.A. No. 24-336-RGA.

3. The Scheduling Order in C.A. No. 21-314-RGA-LDH (consolidated) (D.I. 22), as modified by stipulation and Court Order, shall govern all claims related to the '310 patent in C.A. No. 24-336-RGA, except that:

¹ Plaintiffs' Complaint also alleges that Princeton's ANDA No. 208459 seeks approval for generic versions of Plaintiffs' 10 mg, 15 mg, and 20 mg Xarelto[®] tablets prior to the expiration of U.S. Patent No. 9,539,218 ("the '218 patent"). The Parties do not wish to consolidate Plaintiffs' claims related to the '218 patent.

- a. Princeton Pharmaceutical, Inc. shall be considered a “Defendant Group” under the definition set forth in footnote 2 of paragraph 4(c);
- b. The dates and deadlines in paragraphs 2 and 3 related to Initial Disclosures and Joinder of Other Parties and Amendment of Pleadings shall not apply. Within five business days of the stay being lifted, Princeton and Plaintiffs shall meet and confer regarding revised dates for these deadlines;
- c. Princeton shall be considered to be a party to the Joint discovery served by the defendants in C.A. No. 21-314-RGA-LDH (i.e., Defendants' First Set of Joint Interrogatories to Plaintiffs (Nos. 1-9) and Defendants' First Set of Joint Requests for Production to Plaintiffs (Nos. 1-60) served concurrently April 18, 2022);
- d. Princeton shall not separately serve disclosures under Paragraph 4(d) of the Default Standard in connection with the '310 patent. Princeton shall adopt the invalidity contentions made by the defendants in C.A. No. 21-314-RGA-LDH (consolidated) under Paragraph 4(d) of the Default Standard (i.e., Defendants' Joint Invalidity Contentions served February 28, 2022), and the identification of references and combinations of references made by the defendants in C.A. No. 21-314-RGA-LDH (consolidated) under paragraph 4(g)(iii) of the Scheduling Order and Paragraph 4(d) of the Default Standard (i.e.: (i) Defendants’ Prior Art Narrowing served on behalf of defendants Mylan and Teva on October 14, 2022; (ii) the email bearing the subject line “In re Xarelto (rivaroxaban) U.S. Patent No. 10,828,310 Patent Litigation – Defendants’ references and combinations (Lupin, Taro,

DRL”);² and/or (iii) the grounds set forth in IPR2022-00517 (specifically, the Petition for Inter Partes Review of U.S. Patent No. 10,828,310; the Decision Granting Institution of Inter Partes Review; and the Final Written Decision Determining All Challenged Claims Unpatentable).

- e. All dates and deadlines held in abeyance as a result of the Stay Orders shall remain subject to the stay (C. A. No. 21-314-RGA-LDH, D.I. 144, 153) and shall be revised accordingly in the event that the stay is lifted; and
- f. Paragraphs 8–10 shall not apply. Plaintiffs and Princeton will not separately engage in *Markman* briefing in connection with the ’310 patent, and the Stipulation and Order regarding claim construction in C.A. No. 21-314-RGA-LDH (consolidated) (D.I. 72, 73) shall apply to all claims related to the ’310 patent.

4. The Stipulated Protective Order in C.A. No. 21-314-RGA-LDH (consolidated) (D.I. 36, 37) shall apply.

² Princeton understands there are multiple groups of references and combinations of references disclosed by defendants in C.A. No. 21-314-RGA-LDH (consolidated), and Plaintiffs understand that Princeton may join either or both groups. Princeton further understands there is a dispute as to whether all defendants should have provided a single, joint identification of references and combinations of references under paragraph 4(g)(iii) of the Scheduling Order. Princeton’s adoption of the identification of references and combinations of references made by defendants is without prejudice to Plaintiffs’ ability to object to defendants’ disclosure of anything more than a single, joint identification of references and combinations of references that does not exceed the limit in paragraph 4(g)(iii) of the Scheduling Order.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

Jack B. Blumenfeld (#1014)
Rodger D. Smith (#3778)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
rsmith@morrisnichols.com
dfahnestock@morrisnichols.com

*Attorneys for Plaintiffs Bayer Intellectual
Property GmbH, Bayer Pharma AG, Bayer
AG, and Janssen Pharmaceuticals, Inc.*

HEYMAN ENERIO GATTUSO & HIRZEL, LLP

/s/ Dominick T. Gattuso

Dominick T. Gattuso (#3630)
300 Delaware Ave., Suite 200
Wilmington, DE 19801
Phone: (302) 472-7300
dgattuso@hegh.law

*Attorney for Defendant Princeton
Pharmaceutical, Inc.*

SO ORDERED this 21st day of November, 2024.

/s/ Richard G. Andrews

UNITED STATES DISTRICT JUDGE